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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/801,752	03/09/2001	Gerhard Schmidmaier	8932-148	8071

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EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/801,752	SCHMIDMAIER ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-59* is/are pending in the application.

4a) Of the above claim(s) *32-59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Amendment after Final and the Applicant's Remarks/Response, both filed 05/27/04 is acknowledged.

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is *withdrawn.*

Claims 1-31 are pending. Claim 1 has been amended. Claims 32-59 were previously withdrawn. Claims 1-31 are rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5, 7-19 and 21-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arm *et al.* (WO 93/20859).

Arm et al. teach implants and prosthetic devices having an outer surface coated with biodegradable polymeric films, which comprise polylactic acid/polyglycolic acid copolymers, therapeutically effective amounts of growth factors, active agents and carriers, wherein the polymeric films have a preferred thicknesses of less than about 50 microns. The films may be affixed to the outer surface of the implant or prosthetic device, which include a screw, pin, plate, rod or artificial joint component. The films and rods are therapeutically useful for promoting tissue growth and repair, particularly for enhancing repair of bone fractures (see page 3 line 32 through page 7, line 10) and abstract and claims.

According to Arm, degradation of the film and consequent release of growth factors there from can be modulated by adjusting such film parameters as molecular weight, copolymer structure, copolymer ratio and thickness. In general, the film will be formulated using a copolymer having a molecular weight between 10,000 and 200,000 Daltons. Film thicknesses of less than about 50 microns are preferred. Figure 1 illustrates a 40-50 micron film of PLA/PGA random copolymer of approximately 100,000 molecular weight (page 6, line 28 through page 7, line 5).

Suitable polypeptide growth factors include PDGF, TGF-alpha, TGF-beta, IGF-I, bFGF, aFGF, EGF and the like. Growth factors may be used singly or in combination with one another (page 7, line 6-17). Suitable biodegradable polyester films include polylactic acid, polyglycolic acid, polydioxanone or polylactic acid/polyglycolic acid copolymer films (page 5, lines 10-19).

In addition to the copolymers, growth factors and carriers, the biodegradable films may include other active or inert components. Of particular interest are those agents that promote tissue growth or infiltration. Agents that promote bone growth, such as morphogenic proteins, osteogenin and NaF, for example can be included (page 11, line 32 through page 12, line 4).

Regarding the amount of polymer employed per ml of solvent, Arm in Example 1, page 15, demonstrates the teaching of polylactic acid and polylactic acid-polyglycolic acid films that were solvent cast by dissolving approximately 340 mg of polymer granules in 10 ml of chloroform at room temperature and allowing the solvent to evaporate completely in an air hood.

With respect to the instant percentages (0.1-10%) and instant combinations of growth factor, it appears that the amounts taught by Arm (0.0375 and 1.5 micrograms per mg of copolymer – pg 12, lines 13-24) fall within the applicant's claimed ranges. Furthermore, one of ordinary skill in the art could determine suitable ranges through routine or manipulative experimentation to obtain the best possible results. There is no criticality seen in the amounts of growth factor employed since Arm explicitly teaches similar amounts for a similarly intended purpose. Furthermore, there is no criticality seen in the

particular combination of growth factors, since Arm clearly suggests at page 7, lines 8-10, that the growth factors may be used singly or in combination. One of ordinary skill would select a suitable growth factor or a combination of growth factors, based on the intended purpose at hand.

Claims 1, 2, 4, 5, 8-10 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eitenmuller *et al.* (US Pat. No. 4,610,692).

Eitenmuller et al. teach an implant for filling bone cavities and fixing bone fragments in a living body comprising at least one coating of predetermined thickness, about 4 microns to about 30 microns, of a biodegradable substance selected from at least one of polymethacrylate, polylactide, polydextran and cellulose-based substances, wherein the implant also comprises at least one therapeutically active ingredient (see reference column 3, line 10 through col. 4, line 36); (col. 6, lines 14-25); (col. 7, lines 23-44); and claims.

Claims 1-6, 8-12 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Healy *et al.* (US Pat. No. 5,670,161).

Healy teach an expandable, biodegradable stent for use within a body lumen comprising a hollow tube made from a copolymer of L-lactide and caprolactone, wherein the stent incorporates surface coatings or thin films having a thickness of about 25 microns and whereby suitable polymers include polyethylene glycol, polyvinyl alcohol, polyvinyl pyrrolidone, polymethacrylic acid and polyacrylamide that are blended and copolymerized with biodegradable

materials. The film may coat only surfaces of the stent or may extend over the micro-machined perforations in the stent. The stent may also desirably incorporate one or more drugs, growth factors and inhibitors (see reference column 5, lines 27-60); (col. 10, lines 10-48); and claims.

Response to Arguments

Applicant's arguments filed 05/27/04 have been fully considered and are persuasive. The Applicant requested withdrawal of the Final rejection of claims 1-31 as being premature, since new grounds of rejection were introduced. These arguments were found persuasive based on the 35 USC §103(a) rejection of claims not previously rejected under §103(a) and in the interest of justice, the final Office Action has been withdrawn. This would permit Applicant by right to present any showing of non-obviousness for claims under §103(a).

With regard to Arm et al. (WO 93/20859) the Applicant argued, "Arm does not disclose, teach or suggest an implant having a "varnish-like" coating as recited by claim 1. In contrast to the varnish-like coating, Arm discloses wrapping a pre-prepared biodegradable film around surgical screws, rods, pins, plates and the like. Although the Arm application refers to its wrapped films as "being useful for coatings for prosthetic devices and surgical implants" such is not understood to disclose, teach or suggest the 'varnish-like' coating of claim 1."

These arguments have been fully considered but were not found to be persuasive. The teachings of Arm et al. have been delineated above. The Applicant's use of "varnish-like" in claim 1 has been considered, and given a reasonable definition of a coating formulation wherein the solvent evaporates and a film is formed thereof. Further, as the Applicant admits, Arm et al. do teach that their wrapped films are 'useful for coatings for prosthetic devices and surgical implants'. Hence, the prior art teaches a similar formulation for the same field of endeavor and to solve the same problem as that desired by Applicants. No invention is seen in Applicant's use of "varnish-like" coating as the prior art clearly teaches useful coating compositions for implants, surgical devices and the like.

Next, the Applicant argued regarding the Eitenmuller Patent (4,610,692) stating, "Eitenmuller does not disclose, teach or suggest 'an implant comprising a body having a varnish-like biodegradable polymer coating of a thickness of 100 microns or less, wherein at least a portion of the body has a substantially constant physiochemical state under physiological conditions in vivo as recited by claim 1. The coated implant of Eitenmuller does not have a substantially constant physiochemical state under physiological conditions in vivo. Rather, the implant of Eitenmuller is designed to release at least one therapeutically-active ingredient which is distributed among the pores within the implant."

These arguments have been fully considered but were not found to be persuasive. The teachings of Eitenmuller et al. have been delineated above. With regards to the term "varnish-like" in claim 1, given a reasonable definition of

a coating formulation wherein the solvent evaporates and a film is formed thereof. The prior art teaches an implant for filling bone cavities and fixing bone fragments in a living body, wherein at least one coating of predetermined thickness is contained having about 4 microns to about 30 microns, which the Examiner notes reads on instant claim 1 which requires a coating having a thickness of 100 microns or less. The art clearly teaches a similar formulation for the same field of endeavor and to solve the same problem as that desired by Applicants. No criticality has been established in the instant coating thickness since the prior art initially teaches similar or overlapping coating thicknesses. In regards to the argument that the 'Eitenmuller does not have a substantially constant physiochemical state under physiological conditions in vivo", these arguments were not found to be persuasive, since the art teaches an implant formulation comprising similar components and hence, the properties imparted by those components would also be the same as those desired by Applicants.

Lastly, the Applicant argued regarding the Healy Patent (US 5,670,161) stating, "Healy does not disclose, teach or suggest 'an implant comprising a body having a varnish-like biodegradable polymer coating of a thickness of 100 microns or less, wherein the body has a substantially constant physiochemical state under physiological conditions in vivo as recited by claim 1. Rather, Healy discloses a biodegradable stent."

These arguments have been fully considered but were not found to be persuasive. The teachings of Healy et al. have been delineated above. The stent incorporates surface coatings or thin films having a thickness of about 25

microns and the film may coat only surfaces of the stent or may extend over the micro-machined perforations in the stent. The coating thickness taught by Healy (25 microns) reads on instant claims requiring 100 microns or less. Furthermore, the term "varnish-like" is relative in terms that it does not provide sufficient definition as to distinguish over the polymer coatings of the prior art. The properties imparted by the prior art coatings would provide for similar properties as those obtained with the varnish-like coating. In addition, the argument that the art does not teach a 'substantially constant physiochemical and physiological conditions in vivo' is not persuasive since the art teaches an implant formulation comprising similar components in the same field of endeavor and to solve the same problem, hence, the properties imparted by those components would also be the same as those desired by Applicants. Thus, the instant invention remains obvious and unpatentable over the prior art of record.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The

fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

hns 6.14.

June 14, 2004

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600